

This is a preview of "ISO 21649:2006". Click here to purchase the full version from the ANSI store.

First edition
2006-06-01

Needle-free injectors for medical use — Requirements and test methods

*Injecteurs sans aiguille à usage médical — Exigences et méthodes
d'essai*



Reference number
ISO 21649:2006(E)

© ISO 2006

This is a preview of "ISO 21649:2006". [Click here to purchase the full version from the ANSI store.](#)

PDF disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.

© ISO 2006

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

This is a preview of "ISO 21649:2006". [Click here to purchase the full version from the ANSI store.](#)

Contents

Page

Foreword.....	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions.....	2
4 Symbols and abbreviated terms	4
5 Requirements	5
5.1 General requirements.....	5
5.2 Noise requirements	6
5.3 Dose specification requirements	6
5.4 Uncertainty of measurements and conformance with specifications.....	7
5.5 Performance profile requirements	7
5.6 Test requirements.....	7
6 Test methods.....	10
6.1 General.....	10
6.2 Test procedures	11
6.3 Test conditions	18
6.4 Test evaluations.....	19
7 Test report	20
8 Information supplied by the manufacturer	21
8.1 General.....	21
8.2 Marking	21
8.3 Instructions for use	22
Annex A (informative) Two-sided tolerance limit factors (k).....	23
Annex B (informative) Examples of accuracy limit calculations and random settings	28
Annex C (informative) Correspondence between ISO/IEC standards and EN standards.....	29
Annex ZA (informative) Relationship between this International Standard and the Essential Requirements of EU Directive 93/42/EEC.....	30
Bibliography	32

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 21649 was prepared by Technical Committee ISO/TC 84, *Devices for administration of medicinal products and intravascular catheters*.

This is a preview of "ISO 21649:2006". [Click here to purchase the full version from the ANSI store.](#)

Introduction

This International Standard applies to needle-free injectors primarily intended to administer medicinal products to humans. Because of the anticipated variation in the designs of such a broad array of devices, this International Standard is promulgated more as a “horizontal” rather than a “vertical” one. Thus, it will tend to specify the results of the design effort instead of the physical and construction requirements used as the basis for device design, so that innovation in achieving the intended purposes is not unnecessarily restricted.

Standards of this nature intentionally avoid addressing more than the most basic elements regarding the safety and performance of needle-free injector devices in humans. Any intended labelling of such devices indicating their use to deliver medicinal products into the body or into specified tissue compartments thereof (e.g., intramuscular, subcutaneous or intradermal), or for the administration of specific pharmaceutical drugs or vaccines, shall fall under the authority of national governments or supranational agencies regulating the manufacture and marketing of medical devices and pharmaceutical products. Such standards are expected to be supplemented by additional requirements and may occasionally be superseded by such regulatory authorities. Despite certain advantages for intentional interchangeability for dose chambers designed for different needle-free injection systems, as well as the potential risks of inadvertent interchangeability, these standards avoid setting forth design specifications for the uniform size, shape and interface of such dose chambers. This issue is left for future initiatives to build upon the standards promulgated herein.

The sampling plans for inspection selected for this International Standard are intended to verify the design, at a high confidence level, i.e., the manufacturer's ability to manufacture one “lot” of needle-free injectors, which conforms to the critical product attributes. The sampling plan does not replace the more general manufacturing quality systems, including lot release, which appear in standards on quality systems, e.g. the ISO 9000 series or ISO 13485.